

EXHIBIT 9

EPIDEMIC OF PRESCRIPTION DRUG OVERDOSE IN OHIO

DID YOU KNOW?

- In 2007, unintentional drug poisoning became the leading cause of injury death in Ohio, surpassing motor vehicle crashes and suicide for the first time on record. This trend continued in 2008. (See Figure 1)
- Among the leading causes of injury death, unintentional poisonings increased from the cause of the fewest number of annual deaths in 1999 (369 deaths) to the greatest in 2008 (1,568).¹ (See Figure 2)
- From 1999 to 2008, Ohio's death rate due to unintentional *drug poisonings* increased 350 percent, and the increase in deaths has been driven largely by prescription drug overdoses. In Ohio, there were 327 fatal unintentional drug overdoses in 1999 growing to 1,473 annual deaths in 2008.
- On average, from 2006 to 2008, approximately 4 people died each day in Ohio due to drug-related poisoning.²

There were more Ohio deaths in 2007 and 2008 from unintentional drug-related poisoning than from motor vehicle crashes!



Figure 1. Number of deaths from MV traffic and unintentional drug poisonings by year, Ohio, 2000-2008^{1,2}

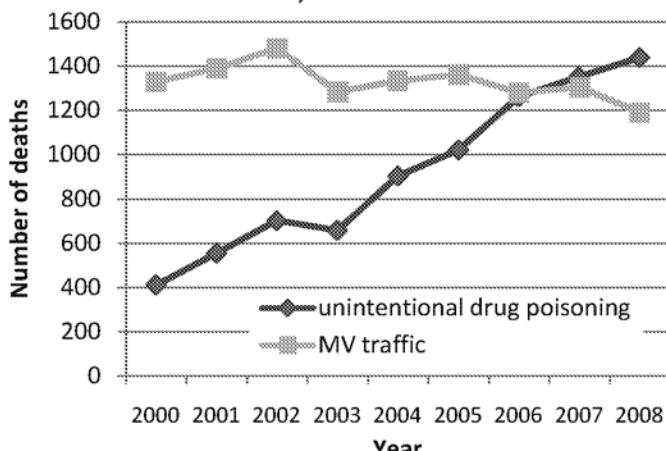
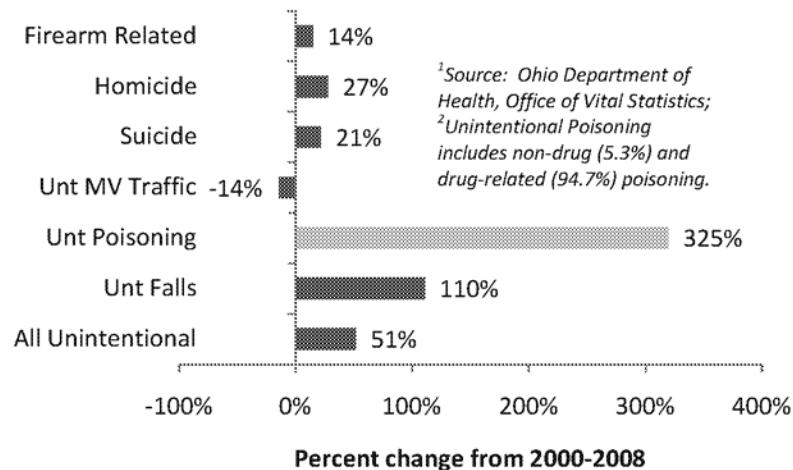


Figure 2 . Percent change in death rate per 100,000 for leading causes of injury, Ohio 1999-2008^{1,2}



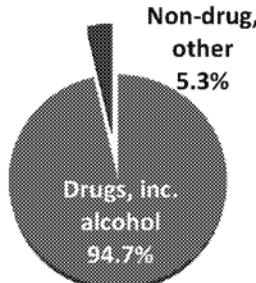
¹Source: Ohio Department of Health, Office of Vital Statistics

²Source: Ohio Department of Public Safety

DRUGS AND MEDICATIONS ARE THE LEADING CAUSE OF POISONING DEATH:

- Nearly all (94.7 percent) unintentional poisoning deaths in Ohio from 2000-2008 were due to drugs.¹ (See Figure 3)
- More than nine out of 10 (95.7 percent) poisoning hospitalizations in Ohio are due to drugs.²

Figure 3. Percent of all unintentional poisoning deaths due to drugs/medications, Ohio, 2000-08¹



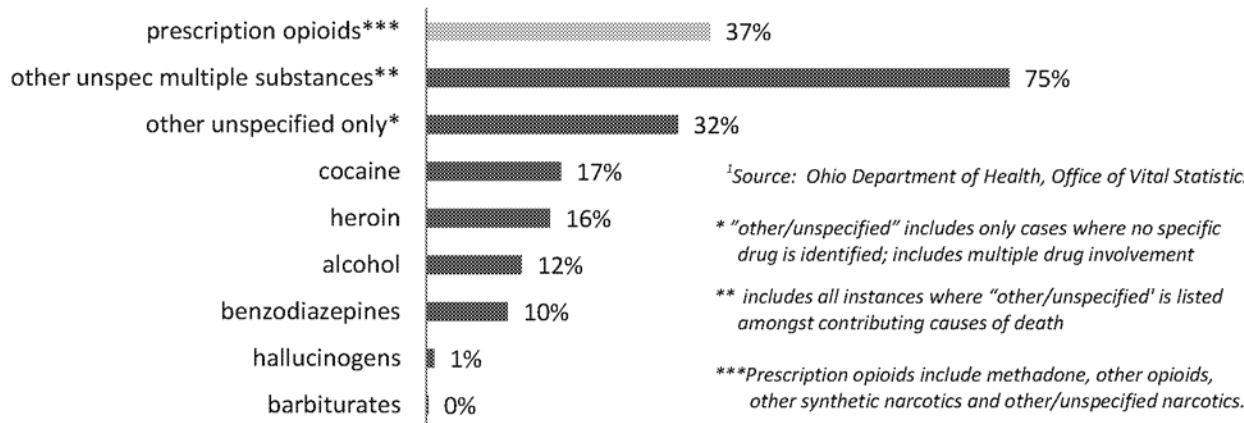
¹Source: Ohio Department of Health, Office of Vital Statistics

ROLE OF PRESCRIPTION PAIN MEDICATIONS:

Prescription opioids (pain medications) are associated with more overdoses than any other prescription or illegal drug including cocaine and heroin.

- Opioids are largely responsible for this alarming increase in drug poisoning death rates.^{ii,iii}
- Opioids were involved in at least 37% percent of all drug poisoning deaths in the Ohio in 2008 (See Figure 4).ⁱ
- The opioids most associated with overdose are methadone, oxycodone (e.g., OxyContin®), hydrocodone (e.g., Vicodin®) and fentanyl.
- Opioids with a long half life (e.g., methadone stays in the body 8 to 60 hours but only relieves pain for 4 to 8 hours) and/or a controlled-release mechanism (e.g., OxyContin®, Duragesic® <fentanyl transdermal>, Opana ER®) have been especially associated with fatal overdoses.
- Prescription opioids were involved in more unintentional overdoses (40%) than heroin and cocaine combined (33%) in Ohio in 2008.

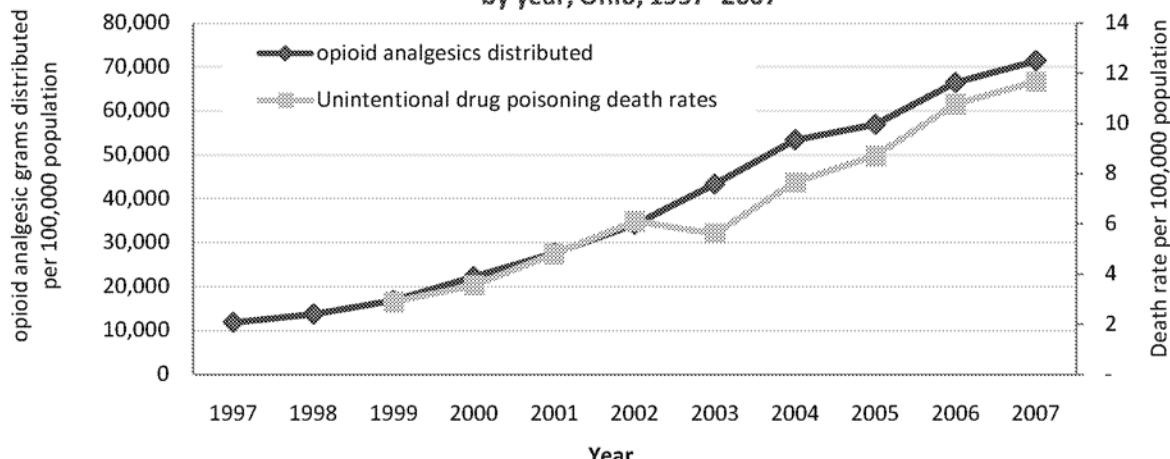
Figure 4. Proportion of all unintentional drug poisoning deaths involving selected drugs, Ohio, 2008¹



There is a strong relationship between increases in sales of prescription opioids and fatal unintentional drug poisoning rates.

- From 1999 to 2007 in Ohio, there were increases of 304 percent and 325 percent, respectively in the unintentional drug poisoning death rate and total grams of prescription opioids distributed per 100,000 population. (See Figure 5)

Figure 5. Unintentional fatal drug poisoning rates¹ and distribution rates of prescription opioids^{2,3} in grams per 100,000 population⁴ by year, Ohio, 1997 -2007⁵



Sources: ¹Ohio Vital Statistics; ²DEA, ARCOS Reports, Retail Drug Summary Reports by State, Cumulative Distribution Reports (Report 4) Ohio, 1997-2007 http://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.htm ³Calculation of oral morphine equivalents used the following assumptions: (1) All drugs other than fentanyl are taken orally; fentanyl is applied transdermally. 2) These doses are approximately equianalgesic: morphine: 30 mg; codeine 200 mg; oxycodone and hydrocodone: 30 mg; hydromorphone: 7.5 mg; methadone: 4 mg; fentanyl: 0.4 mg; meperidine: 300 mg; ⁴US Census Bureau, Ohio population estimates 1997-2007. ⁵preliminary data for 2007

MULTIPLE DRUG USE:

Use of multiple drugs, especially multiple depressants, is a risk factor for unintentional overdose.

- Most “other/unspecified” drug deaths are associated with multiple drug use.
- In 2008, at least 75% of all unintentional drug poisoning deaths involved multiple drugs (See Figure 4).

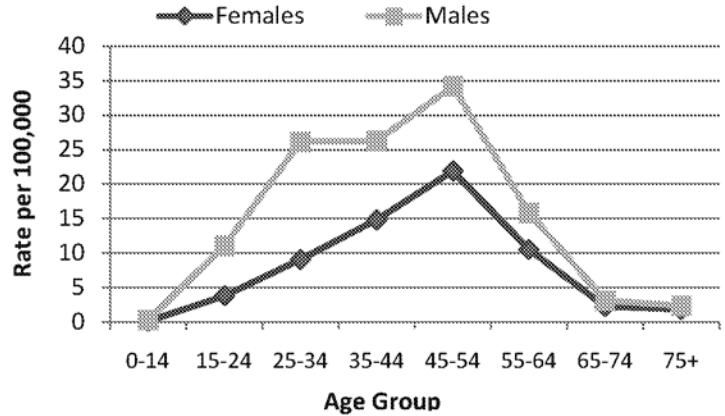
ROLE OF OTHER DRUGS AND RISK FACTORS:

- Ten percent of the unintentional drug poisoning deaths in 2008 in Ohio involved benzodiazepines (sedative/anti-anxiety) and twelve percent involved alcohol. Only 1% involved hallucinogens and less than 1% involved barbiturates (Figure 4).
- About the same proportion of drug poisoning deaths involved cocaine (17%), including crack cocaine, and heroin (16%) in 2008.
- At this point, nearly all substances including anti-depressants, cardiovascular drugs, antihistamines, muscle relaxants and anticonvulsants have been involved in fatal overdoses.

WHO IS AFFECTED?

- Death rates from unintentional drug/medication-related poisoning are highest for Ohioans ages 45-54, with rates for males 1.5 times greater than the rates for females. (See Figure 6)
- White males have the highest death rates from unintentional opioid poisoning; however, females represent the fastest growing group at risk.ⁱ
- In 2007, 26.5 percent of high school students reported using a prescription drug without a doctor’s prescription one or more times during their life.^{vi}

Figure 6. Average annual unintentional drug/medication poisoning rate¹ by sex, age group, Ohio 2006-2008*



*Source: ODH: Office of Vital Statistics

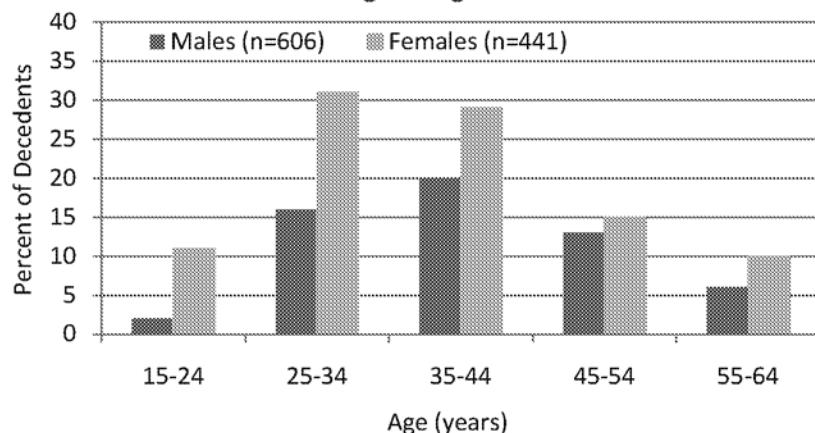
CONTRIBUTING FACTORS AND CURRENT TRENDS:

- According to the Institute for Safe Medication Practices, half of the prescriptions taken each year in the United States are used improperly. In addition, changing medical and advertising practices have contributed to widespread use of prescription drugs across all levels of the population. Many of these prescription drugs may be misused or abused.
- Societal and medical trends that lead to this problem include changes in clinical prescribing practices for pain medication, changes in marketing of medications directly to consumers, overmedication and mixing medications, substance abuse, widespread diversion of medications, deception of providers including doctor shopping and prescription fraud, illegal online “pharmacies,” unscrupulous providers (e.g., “pill mills”), medication errors and improper storage and disposal of excess medications.^{vii, viii}

DOCTOR SHOPPING AND DIVERSION:

Sixteen percent of 2008 unintentional poisoning decedents had a history *doctor shopping* (filled prescriptions from at least 5 different prescribers per year). More than one-quarter of female decedents age 25-44 exhibited doctor shopping behavior. (See Figure 7)

Figure 7. Percent of 2008 unintentional poisoning decedents who doctor shopped between 2006-2008 by age and gender¹⁻⁶



¹Average 5 prescribers per year from 1/1/06 to 12/31/08.

²No doctor shoppers over age 65 for males or females

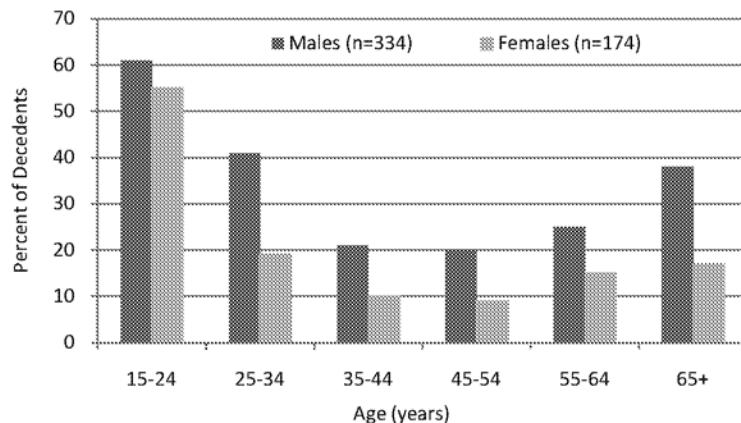
³Prescriptions filled outside of Ohio not included

⁴Included decedents with at least one script filled in OARRS 1/1/06-12/31/08

Sources: ⁵Ohio Vital Statistics; ⁶Ohio Automated Rx Reporting System database, Ohio State Board of Pharmacy, Columbus, Ohio (August 12, 2009).

Among 2008 drug poisoning decedents with a prescription opioid listed on their death certificate, **25 percent** obtained the opioid through *diversion* (no record of filling a prescription for opioid in Ohio within two years prior to death). (See Figure 8)

Figure 8. Percent of 2008 unintentional poisoning decedents with prescription opioid on death certificate and no opioid prescription filled from 2006 to 2008 by age and gender¹⁻⁴



¹Analysis confined to decedents 15 years and older

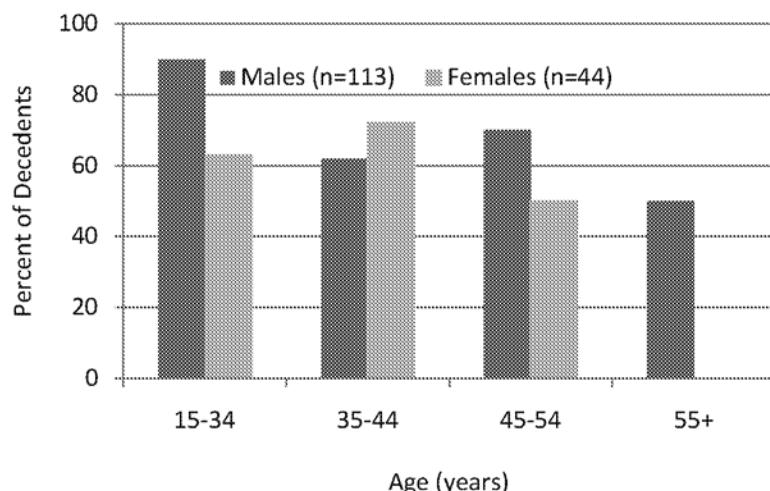
²Prescriptions filled outside of Ohio not included

Sources: ⁵Ohio Vital Statistics; ⁶Ohio Automated Rx Reporting System database, Ohio State Board of Pharmacy, Columbus, Ohio (August 12, 2009).

METHADONE DIVERSION

Examining one opioid, methadone, nearly 71% of 2008 unintentional poisoning decedents obtained the methadone through *diversion* (no record of filling a prescription for methadone in Ohio within two years prior to death). (See Figure 9) Methadone appears to be diverted with more frequency than other opioids. This is concerning considering methadone's long half-life and other unique properties that create a higher risk for fatal overdose.

Figure 9. Percent of 2008 unintentional drug poisoning decedents with methadone on death certificate and no script filled for methadone since 2006 by age and gender¹⁻⁴



¹Analysis confined to decedents 15 years and older

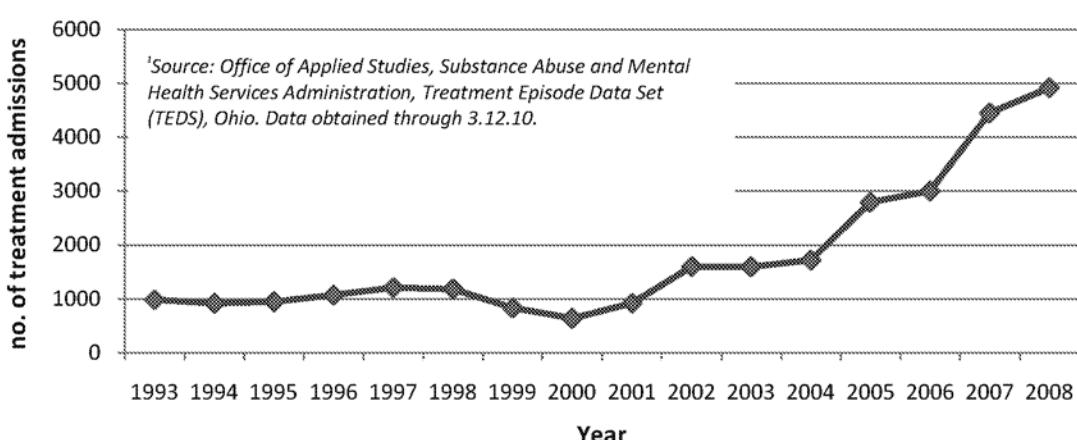
²Prescriptions filled outside of Ohio not included

Sources: ⁵Ohio Vital Statistics; ⁶Ohio Automated Rx Reporting System database, Ohio State Board of Pharmacy, Columbus, Ohio (August 12, 2009).

MORE CONSEQUENCES TO OHIOANS:

Another consequence of these trends is that admissions for non-heroin opioid substance abuse treatment are on the rise. In the past decade, admissions have increased more than 300% in Ohio. (See Figure 10)

Figure 10. Number of substance abuse treatment admissions for non-heroin opioids by year, Ohio, 1993-2008¹



COSTS TO OHIOANS:

In addition to the tragic loss of human life, drug overdoses are associated with high direct and indirect costs. Unintentional fatal poisonings cost Ohioans **\$3.5 billion** on average each year; while non-fatal, hospital-admitted poisonings cost an additional **\$31.9 million**. These costs include medical, work loss and quality-of-life loss.

Estimated average annual costs of fatal and non-fatal, hospital-admitted unintentional drug overdose in Ohio ¹		
Type of Costs	Fatal Costs ²	Non-fatal, hospital admitted costs ³
Medical	\$4.9 million	\$19.1 million
Work loss	\$1.2 billion	\$5.2 million
Quality-of-Life loss	\$2.2 billion	\$7.6 million
Total	\$3.5 Billion	\$31.9 Million

¹Source: Children's Safety Network Economics & Data Analysis Resource Center, at Pacific Institute for Research and Evaluation, 2005; ²Year 2004 Dollars, Based on 2004-2007 average Ohio incidence ³Year 2005 Dollars, Based on Year 2003 Ohio incidence

WHAT CAN BE DONE TO ADDRESS THIS ISSUE?

AT THE LOCAL LEVEL...

- Form a poisoning/overdose coalition to address the problem at the county or regional level.
 - Members should include local leadership from health departments, coroners, health care professionals, alcohol and drug addiction treatment centers, law enforcement agencies, health professional associations, mental health agencies, hospitals, pharmacists, private citizens, businesses, media, and other interested and relevant organizations or agencies.
- Work with local partners to implement social marketing campaigns to educate the public about prescription drug abuse and misuse.
- Conduct education campaigns specifically for local populations particularly at risk.
- Develop training programs for use in reaching adults in a variety of settings (e.g. places of employment, professional conferences/meetings, doctor's offices, dentists' offices, etc.)
- Conduct proper prescription drug storage and disposal programs such as Drug Take Back programs.
- Establish county Poison Death Review (PDR) committees to identify the circumstances surrounding drug poisoning/overdose deaths to provide insight into prevention.

AT THE STATE LEVEL...

- Fund social marketing campaigns to educate the public about prescription drug abuse and misuse.
- Identify and/or develop model education campaigns specifically for populations particularly at risk.
- Develop training programs for use at the local level in reaching adults in a variety of settings (e.g. places of employment, professional conferences/meetings, doctor's offices, dentists' offices, etc.)
- Provide support and information to local organizations and coalitions for conducting Drug Take Back programs.
- Encourage health care and allied medical professional organizations and state boards to initiate education campaigns for their members regarding the problem of unintentional overdose deaths.
- Develop a tool kit for use by health care providers to educate all patients being prescribed pain medication.
- Adopt a Screening Brief Intervention Referral Treatment (SBIRT) protocol within health care and workplace settings to screen for misuse and/or abuse of prescribed medications.
- Initiate efforts to increase the capacity for treatment for opioid addiction.
- Promote collaborative efforts among law enforcement agencies to enforce prescription drug fraud statutes currently in effect in Ohio.
- Promote the coordination of investigations of fraud committed by individuals or pain clinics among local law enforcement, state regulating agencies, and state and federal investigative agencies.
- Improve linkage of data systems among state agencies (e.g. ODH, BOP, Medicaid/ODJFS, ODADAS, Ohio Department of Insurance, etc.)
- Collaborate with other states on drug monitoring systems.
- Provide funding for a statewide coroner reporting system.
- Create a data action group to review current surveys and data collection methods and identify gaps in knowledge and develop specific questions to address these needs.
- Explore the feasibility and potential benefits of legislation/regulations to:
 - Create licensing standards for pain management clinics.
 - Institute mandatory continuing education credits in pain management for health care professionals for licensure renewal.
 - Require course work in substance use disorders, prevention and treatment in the college curriculum for any medical professional or allied health care degree.
 - Require all physicians and other prescribers to register with and use the OARRS administered by the Board of Pharmacy (BOP).
 - Implement E-prescribing in Ohio.
 - Allow for reimbursement of SBIRT interventions from Medicaid and insurance companies.
 - Ensure the development, adoption, and implementation of pain management guidelines in all health care systems.
 - Create 911 Good Samaritan Immunity Laws that legalize the use of naloxone by lay persons and protects them from prosecution.
 - Increase the use of "Drug Courts" as an alternative to incarceration for illegal use/abuse of prescription drugs.
 - Require photo ID when picking up prescriptions for controlled substances.
- **Support these and other initiatives that are identified in the attached recommendations from the Poison Action Group (PAG)/New and Emerging Drug Trends Work Group (NEDTW). The PAG/NEDTW was convened by the Ohio Injury Prevention Partnership in conjunction with the Ohio Department of Alcohol and Drug Addiction Services and the Ohio Department of Health.**

RESOURCES:

- Injury Prevention Program, Ohio Department of Health:
<http://www.odh.ohio.gov/odhPrograms/hprr/injprev/OVIPP.aspx>
- National Poison Help: <http://poisonhelp.hrsa.gov/index.htm>
- Food and Drug Administration, Center for Drug Evaluation and Research:
<http://www.fda.gov/cder/indes.html>
- Office of National Drug Control Policy, Proper Disposal of Medications Factsheet:
http://whitehousedrugpolicy.gov/drugfact/factsht/proper_disposal.html
- National Safety Council Poison Prevention Information:
<http://www.nsc.org/resources/issues/poison.aspx>
- Poison Prevention Week Council web site: <http://www.poisonprevention.org/>
- Rx Use Only as Directed – Utah Department of Health: <http://www.useonlyasdirected.org/>
- “A Guide to Safe Use of Pain Medicine”:
<http://www.fda.gov/consumer/updates/painmeds022309.html>

Sources:

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- ii. Centers for Disease Control and Prevention, National Center for Health Statistics. Compressed Mortality File 1999-2005.
- iii. Paulozzi, LJ, Budnitz, DS, Xi, Y. Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiology and Drug Safety*. 2006; 15:618-627.
- iv. Dasgupta N, Jonsson, FM, Brownstein JS. Accidental opioid poisoning mortality, United States, 1999-2004.
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- viii. Food and Drug Administration. FDA Public Health Advisory, Methadone Use for Pain Control May Result in Death and Life-Threatening Changes in Breathing and Heart Beat. Bethesda, MD: Center for Drug Evaluation and Research; 2007 November 27. <http://www.fda.gov/cder/drug/advisory/methadone.htm>
- ix. Sanford K. *Findings and Recommendations of the Task Force to Prevent Deaths from Unintentional Drug Overdoses in North Carolina, 2003*. In: N.C. Injury and Violence Prevention Branch - North Carolina Department of Health and Human Services, ed.: <http://www.ncpublichealth.com/>; >2004.
- x. Centers for Disease Control and Prevention. Unintentional poisoning deaths--United States, 1999-2004. *MMWR Morb Mortal Wkly Rep* 2007;56(5):93-6. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5605a1.htm>
- xi. Food and Drug Administration. FDA Public Health Advisory, Important Information for the Safe Use of Fentora (fentanyl buccal tablets). Bethesda, MD: Center for Drug Evaluation and Research; 2007 September 26. <http://www.fda.gov/cder/drug/infopage/fentanyl/default.htm>
- xii. Centers for Disease Control and Prevention. Nonpharmaceutical fentanyl-related deaths--multiple states, April 2005-March 2007. *MMWR Morb Mortal Wkly Rep* 2008;57(29):793-6. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5729a1.htm>
- xiii. Alarming Rise in Unintentional Drug/Medication-related Poisoning Deaths in Ohio. Injury Prevention Program, Ohio Department of Health.

Produced by the Violence and Injury Prevention Program, Ohio Department of Health.
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